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Date: September 5, 2003

By:

Carol A. See

PATENT
Docket No. GC636-2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)

Marc Kolkman)

Serial No.: 09/975,132)

Filed: October 9, 2001)

For: Enhanced Secretion of a Polypeptide)
by a Microorganism)

Group Art Unit: 1641

Examiner: Unassigned

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Information Disclosure Statement

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants submit herewith patents, publications or other information (listed on the attached Form PTO-1449 and attached thereto) of which they are aware, that they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement:

- (a) ☐ accompanies the new patent application submitted herewith. 37 CFR §1.97(a).
- (b) ☐ is filed within three months after the filing date of the application or within three months after the date of entry into the national stage of a PCT application as set forth in 37 CFR §1.491.
- (c) ☒ as far as is known to the undersigned, is filed before the mailing date of a first Office Action on the merits.
- (d) ☐ is filed after the first Office Action and more than three months after the application filing date or PCT national stage date of entry filing but, as far as is known to the undersigned, prior to the mailing date of either a final

rejection or a notice of allowance, whichever occurs first, and is accompanied by either the fee (\$180.00) set forth in 37 CFR §1.17(p) or a certification as specified in 37 CFR §1.97(e), as checked below. Authorization to charge Deposit Account No. 07-1048 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement is provided in the Transmittal Letter submitted herewith in duplicate.

(e) ☐ is filed after the mailing date of either a final rejection or a notice of allowance, whichever occurred first, and is accompanied by authorization (in the Transmittal Letter submitted herewith in duplicate) to charge Deposit Account No. 07-1048 the fee (\$180.00) set forth in 37 CFR §1.17(l)(1) and a certification as specified in 37 CFR §1.97(e), as checked below. **This document is to be considered as a petition requesting consideration of the Supplemental Information Disclosure Statement.**

[If either of boxes (d) or (e) is checked above, the following "certification" under 37 CFR §1.97(e) may need to be completed.] The undersigned certifies that:

☐ Each item of information contained in the Information Disclosure Statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

☐ No item of information contained in this Information Disclosure Statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

A copy of the items on Form PTO-1449 is supplied: PCT International Search Report for PCT/US 01 42647, filed September 10, 2001 with attached patents and publications.

☒ each ☐ none ☐ only those listed below:

Those patent(s) or publication(s) which are marked with an asterisk (*) on the attached Form PTO-1449 (**Books not sent**) are not supplied. Complete bibliographic information is unknown or unavailable. The cited publications are books or reference manuals and are commonly available. Reproduction of such publications would result in a voluminous submission.

A concise explanation of relevance of the items listed on PTO-1449 is:

- ☐ not given
- ☐ given for each listed item
- ☐ given for only non-English language listed item(s)
- ☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

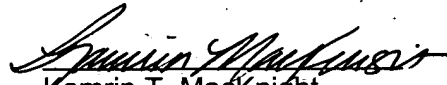
The Examiner is reminded that a "concise explanation of the relevance" of the submitted prior art "may be nothing more than identification of the particular figure or paragraph of the patent or publication which has some relation to the claimed invention." MPEP §609.

While the information and references disclosed in this Information Disclosure Statement may be "material" pursuant to 37 CFR §1.56, it is not intended to constitute an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR §1.97(b), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR §1.56(a) exists. It is submitted that the Information Disclosure Statement is in compliance with 37 CFR §1.98 and MPEP §609 and the Examiner is respectfully requested to consider the listed references.

Respectfully submitted,

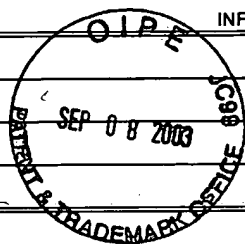
Date: *2 September 2003*


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INFORMATION DISCLOSURE CITATION

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|------------------------------|--|
| Attorney Docket No.: GC636-2 | Serial No.: 09/975,132 |
| Applicant: Mark Kolkman | |
| Filing Date: October 9, 2001 | Group: 1641 |
| Page 1 of 2 | Date of this Submission: September 5, 2003 |



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US PATENT DOCUMENTS

| Examiner's | Document | | | | Sub- | Filing |
|------------|-----------|----------|-------------|-------|-------|--------|
| Initial | Number | Date | Name | Class | Class | Date |
| | 4,923,808 | 5/8/90 | Matteucci | | | |
| | 5,578,464 | 11/26/96 | Lunn et al. | | | |

FOREIGN PATENT DOCUMENTS

| Examiner's | Document | | | | Sub- | Translation |
|------------|--------------|----------|---------|-------|-------|-------------|
| Initials | Number | Date | Country | Class | Class | Yes/No |
| | 0 955,370 A2 | 11/10/99 | EP | | | |
| | WO 99/42121 | 8/26/99 | PCT | | | |

OTHER DOCUMENTS

| Examiner's | |
|------------|--|
| Initials | Author, Title, Date, Pertinent Pages, etc. |
| | Abo, Tatsuhiro et al., « SsrA-mediated tagging and proteolysis of LacI and its role in the regulation of lac operon, » EMBO Journal, 19:3762-3769, 2000. |
| | Arima, Hiduyuki et al., « Enhanced secretion of hydrophobic peptide fused lysozyme by the introduction of N-glycosylation signal and the disruption of calnexin gene in Saccharomyces cerevisiae, » FEBS Letters Vol. 440, no. 1-2, pp. 89-92, 1998. |
| | Atkins, John F. et al., « A case for trans translation, » Nature, 379:769-771, 1996. |
| | Gottesman, Susan et al., « The ClpXP and ClpAP proteases degrade proteins with carboxy-terminal peptide tails added by the SsrA-tagging system, » Genes and Dev., 12:1338-1347, 1998. |
| | Guérout-Fleury, Anne-Marie et al., « Antibiotic-resistance cassettes for Bacillus subtilis, » Gene, 167:335-336, 1995. |
| | *Hale & Marham, The Harper Collins Dictionary of Microbiology, Harper Perennial, Ny, 1991. |
| | Herman, Christophe, et al., « Degradation of carboxy-terminal-tagged cytoplasmic proteins by the Escherichia coli protease HflB (FtsH), » Genes and Dev., 12:1348-1355, 1998. |
| | Jentsch, Stefan, « When Proteins Receive Deadly Messages at Birth, » Science, 271:955-956, 1996. |
| | Karzai, A. Wali et al., « SmpB, a unique RNA-binding protein essential for the peptide-tagging activity of SsrA (tmRNA), » EMBO J., 18:3793-3799, 1999. |
| | Karzai, A. Wali et al., « The SsrA-SmpB system for protein tagging, directed degradation and ribosome rescue, » Nat. Struct. Biol., 7:449-455, no. 7, 2000. |
| | Keiler, Kenneth C. et al., « Role of a Peptide Tagging System in Degradation of Proteins Synthesized from Damaged Messenger RNA, » Science, 271:990-993, 1996. |
| | Kühn, Sabine et al., « The baculovirus expression vector pBSV-8His directs secretion of histidine-tagged proteins, » Gene 162:225-229 9/11/95, XP004042020. |
| | Kunst, F. et al., « The complete genome sequence of the Gram-positive bacterium Bacillus subtilis, » Nature, 390:249-256, 1997. |
| | Muto, Akira et al., « Requirement of transfer-messenger RNA for the growth of Bacillus subtilis under stresses, » Genes Cells, 5:627-635, 2000. |
| | Roche, Eric D. et al., « SsrA-mediated peptide tagging caused by rare codons and tRNA scarcity, » EMBO J., 18:4579-4589, 1999. |
| | *Sambrook, J. et al., Molecular Cloning, A Laboratory Manual, 2nd Ed., Cold Spring Harbor Laboratory Press, Cold Spring Harbor, New York, Ch. 9 & 11 1989 |
| | Simonen, Marjo et al., « Protein Secretion in Bacillus Species, » Microbiological Reviews, American Society for Microbiology, Washington D.C., U.S. Vol. 57, no. 1 3/1/93, pp. 109-137. |
| | *Singleton et al., Dictionary of Microbiology and Molecular Biology, 2 nd ed., John Wiley & Sons, New York, 1994. |

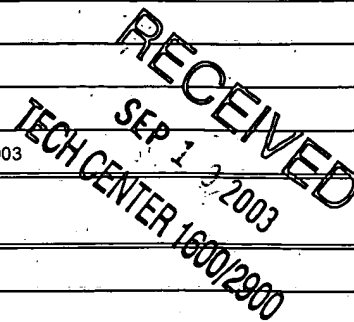
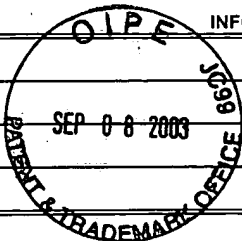
| Examiner | Date Considered |
|----------|-----------------|
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Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

PTO-1449

INFORMATION DISCLOSURE CITATION

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|---|---|
| Attorney Docket No.: GC636-2 | Serial No.: 09/975,132 |
| Applicant: Mark Kolkman | |
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OTHER DOCUMENTS

| Examiner's | |
|---|--|
| Initials | Author, Title, Date, Pertinent Pages, etc. |
| | Tu, Guo-Fen et al., « C-terminal Extension of Truncated Recombinant Proteins in Escherichia coli with a 10Sa RNA Decapeptide, » J. Biol. Chem., 270:9322-9326, 1995. |
| | Udaka, Shigezo et al., « High-Level Secretion of Heterologous Proteins by Bacillus brevis, » Methods In Enzymology, Academic Press, Inc., 217 :23-33, 1993. |
| | Ushida, Chisato et al., « tRNA-like structures in 10Sa RNAs of Mycoplasma capricolum and Bacillus subtilis, » Nucleic Acids Res., 22 :3392-3396, 1994. |
| | Vagner, Valérie et al., « A vector for systematic gene inactivation in Bacillus subtilis, » Microbiology, 144 :3097-3104, 1998. |
| | Van Dijk, Jan Maarten et al., « Non-functional expression of Escherichia coli signal peptidase I in Bacillus subtilis, » J. Gen. Microbiol., 137:2073-2083, 1991. |
| | Van Leen, Rob W. et al., « Production of Human Interleukin-3 Using Industrial Microorganisms, » Biotechnology, 9 :47-52, 1991. |
| | Wiegert, Thomas et al., « SsrA-Mediated Tagging in Bacillus subtilis, » J. Bacteriol., 183 :3885-3889, 2001. |
| | Williams, Kelly P., « The tmRNA Website, » Nucleic Acids Res., 28 :168, 2000. |
| | Williams, Kelly P. et al., « Resuming translation on tmRNA : an unique mode of determining a reading frame, » EMBO J., 18 :5423-5433, 1999. |
| | Wu, Xu-Chu, « Engineering a Bacillus subtilis Expression-Secretion System with a Strain Deficient in Six Extracellular Proteases, » J. Bacteriol., 173 :4952-4958, 1991. |
| | PCT International Search Report |
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| Examiner | Date Considered |
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